

Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX 301-827-6776, or e-mail: reedyk@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12536. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 26, 2001, the committee will discuss new drug application (NDA) 21-332, Symclin™ (pramlintide acetate, Amylin Pharmaceuticals, Inc.) as an adjunctive therapy to insulin to improve glycemic and metabolic control in patients with type 1 or type 2 diabetes mellitus alone or in combination with oral hypoglycemic agents. On July 27, 2001, the committee will discuss NDA 21-318, Fortéo™ (teriparatide injection, rDNA origin, Eli Lilly and Co.) for the treatment of osteoporosis in men and in postmenopausal women.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 20, 2001. Oral presentations from the public will be scheduled between approximately 11 a.m. and 11:30 a.m. each day. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 20, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 31, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-1194-N]

Medicare Program; Meeting of the Practicing Physicians Advisory Council on June 25, 2001

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Practicing Physicians Advisory Council. This meeting is open to the public.

DATES: The meeting is scheduled for June 25, 2001, from 8:30 a.m. until 5 p.m., e.d.t.

ADDRESSES: The meeting will be held in Room 505A, 5th Floor, Hubert H. Humphrey, 200 Independence Avenue, SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Paul Rudolf, M.D., J.D., Executive Director, Practicing Physicians Advisory Council, Room 435-H, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, (202) 690-7874. News media representatives should contact the HCFA Press Office, (202) 690-6145. Please refer to the HCFA Advisory Committees Information Line (1-877-449-5659 toll free)/(410 786-9379 local) or the internet (<http://www.hcfa.gov/fac>) for additional information and updates on committee activities.

SUPPLEMENTARY INFORMATION: The Secretary of the Department of Health and Human Services (the Secretary) is mandated by section 1868 of the Social Security Act to appoint a Practicing Physicians Advisory Council (the Council) based on nominations submitted by medical organizations representing physicians. The Council meets quarterly to discuss certain proposed changes in regulations and carrier manual instructions related to physicians' services, as identified by the Secretary. To the extent feasible and consistent with statutory deadlines, the consultation must occur before publication of the proposed changes. The Council submits an annual report on its recommendations to the Secretary and the Administrator of the Health Care Financing Administration not later than December 31 of each year.

The Council consists of 15 physicians, each of whom has submitted at least 250 claims for physicians' services under Medicare or Medicaid in the previous year. Members of the Council include both participating and nonparticipating physicians, and physicians practicing in rural and underserved urban areas. At least 11 members must be doctors of medicine or osteopathy authorized to practice medicine and surgery by the States in which they practice. Members have been invited to serve for overlapping 4-year terms. In accordance with section 14 of the Federal Advisory Committee Act, this Council automatically terminates two years after its date of establishment, unless the

Council is renewed before the termination date by appropriate agency action. Therefore, terms of more than two years for members are contingent upon the renewal.

The Council held its first meeting on May 11, 1992.

The current members are: Jerold M. Aronson, M.D.; Richard Bronfman, D.P.M.; Joseph Heyman, M.D.; Sandra Hullett, M.D.; Stephen A. Imbeau, M.D.; Angelyn L. Moultrie, D.O.; Derrick K. Latos, M.D. (pending re-appointment); Dale Lervick, O.D.; Sandra B. Reed, M.D.; Amilu Rothhammer, M.D.; Victor Vela, M.D.; and Kenneth M. Viste, Jr., M.D.; and Douglas L. Wood, M.D. The Council chairperson is pending selection.

The agenda will provide for discussion and comment on the following topics:

- Inputs and insights on the draft instructions to implement Advance Beneficiary Notices.
- Physician Regulatory Issues Team (PRIT) update.
- Evaluation and Management Documentation Guidelines (update and discussion on medical review form).
- Physician Participation in Evaluation and Management Guidelines Pilot Studies (How to address issues of miscoding and medical review in the studies).
- Contractor Oversight Issues (provider education, customer service, medical review, and contractor performance evaluation).

For additional information and clarification on the topics listed, call the contact person in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Individual physicians or medical organizations that represent physicians and who wish to be scheduled to make 5-minute oral presentations on agenda issues should contact the Executive Director by 12 noon, June 15, 2001. Testimony is limited to the listed agenda issues only. The number of oral presentations may be limited by the time available. A written copy of the presenter's oral remarks should be submitted to the Executive Director no later than 12 noon, June 18, 2001, for distribution to Council members for review prior to the meeting. Physicians and organizations not scheduled to speak may also submit written comments to the Executive Director and Council members. The meeting is open to the public, but attendance is limited to the space available. Individuals requiring sign language interpretation for the hearing impaired or other special accommodation should contact John

Lanigan (202) 690-7418 at least 10 days before the meeting.

(Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Public Law 92-463 (5 U.S.C. App. 2, section 10(a)) (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 6, 2001.

Thomas A. Scully,

Administrator, Health Care Financing Administration.

[FR Doc. 01-14595 Filed 6-7-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

State Grants for Traumatic Brain Injury

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that about \$1.2 million in fiscal year (FY) 2001 funds is available for up to 14 State Grants for Traumatic Brain Injury (TBI) awards. Grant programs for TBI provide health and other services for people who have sustained a traumatic brain injury. Awards will be made in two categories—Planning Grants, to assist States in developing the infrastructure needed to implement a State TBI program; and a new category of Post Demonstration Grants for States which have successfully completed a TBI Implementation Grant. All grants will be made under the program authority of the Public Health Service Act, Title XII, Section 1252 (42 U.S.C. 300d-52), as amended, and will be administered by the Maternal and Child Health Bureau (MCHB), HRSA. Awards for TBI Planning Grants (CFDA #93.234B) may be approved for up to two years, and range from \$50,000 to \$75,000. Awards for TBI Post Demonstration Grants (CFDA #93.234C) are available for only one year, in amounts up to \$100,000. Funding for these grant categories beyond FY 2001 is contingent upon the availability of funds.

DATES: Entities which intend to submit an application for this grant program are expected to notify MCHB's Division of their intent by June 18, 2001. The deadline for receipt of applications is July 16, 2001. Applications will be considered "on time" if they are either

received on or before the deadline date or postmarked on or before the deadline date. The projected award date is September 29, 2001.

ADDRESSES: To receive a complete application kit, applicants may telephone the HRSA Grants Application Center at 1-877-477-2123 (1-877-HRSA-123) beginning June 4, 2001, or register on-line at: <http://www.hrsa.gov/order3.htm> directly. The Traumatic Brain Injury State Grant Program uses the standard Form PHS 5161-1 (rev. 7/00) for applications (approved under OMB No. 0920-0428). Applicants must use Catalog of Federal Domestic Assistance (CFDA) #93.234B when requesting an application kit. The CFDA is a Government-wide compendium of enumerated Federal programs, project services, and activities which provide assistance. All applications must be mailed or delivered to Grants Management Officer, MCHB: HRSA Grants Application Center, 1815 N. Fort Meyer Drive, Suite 300, Arlington, Virginia 22209; telephone 1-877-477-2123; E-mail: hrsagac@hrsa.gov.

Necessary application forms and an expanded version of this **Federal Register** notice may be downloaded in either Microsoft Office 2000 or Adobe Acrobat format (.pdf) from the MCHB Home Page at <http://www.mchb.hrsa.gov>. Please contact Joni Johns, at 301/443-2088, or jjohns@hrsa.gov, if you need technical assistance in accessing the MCHB Home Page via the Internet.

This notice will appear in the **Federal Register** and or HRSA Home Page at <http://www.hrsa.dhhs.gov/>. **Federal Register** notices are found on the World Wide Web by following instructions at: http://www.access.gpo.gov/su_docs/aces/aces140.html.

Letter of Intent: Notification of intent to apply should be directed to Betty Hastings, M.S.W., by email, bhastings@hrsa.gov; or mail, MCHB, HRSA; Division of Child, Adolescent and Family Health, Parklawn Building, Room 18A-38; 5600 Fishers Lane; Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Betty Hastings, M.S.W., 301/443-5599, or email: bhastings@hrsa.gov (for questions specific to project objectives and activities of the program; or the required Letter of Intent); Marilyn Stewart, 301/443-1440, email mstewart@hrsa.gov (for grants policy, budgetary, and business questions).

SUPPLEMENTARY INFORMATION: Traumatic brain injury (i.e., cranio-cerebral head trauma) is an occurrence of injury to the head arising from blunt or penetrating trauma or from acceleration-

deceleration forces that is associated with any of these symptoms or signs attributed to the injury: Decreased level of consciousness, amnesia, other neurologic or neuropsychologic abnormalities, skull fracture, diagnosed intracranial lesions, or death.

Motor vehicle crashes, falls, violence, and sports injuries are the major causes of TBI; the number one killer and cause of disability for young people in the United States. The Centers of Disease Control and Prevention has found that approximately 5.3 million Americans live with the effects of TBI. About half the estimated 1.9 million Americans who experience TBI each year incur at least short-term disability; 52,000 people die as a result of their injuries and more than 90,000 people sustain severe brain injuries leading to debilitating loss of function. The direct medical costs for treatment of TBI have been estimated at more than \$4 billion annually.

In 1996, Public Law 104-166 established a program of grants to States to carry out TBI demonstration projects to increase access to rehabilitation, employment, education, and other long-term community support services, in addition to health and medical services.

State Grants for TBI support projects by States to implement statewide systems, ensuring access to comprehensive and coordinated TBI Services. These projects are successfully bringing together representatives of relevant State agencies, disciplines, organizations, and consumers.

Until FY 2001, two categories of TBI demonstration grant programs were available—State TBI Planning Grants and State TBI Implementation Grants. To date, 31 States and the District of Columbia have received basic planning support to establish the necessary infrastructure core capacity components needed to develop an Action Plan to improve the State's TBI service system. State TBI planning grantees develop four "core capacity" components, identified as the essential elements in any plan for State implementation of a TBI service system. These include: (1) A statewide TBI Advisory Board; (2) Designated State agency and staff position(s) responsible for State TBI activities; (3) a statewide needs/resource assessment to address the full spectrum of services from initial acute treatment through rehabilitation and long-term community services for individuals with TBI; and (4) a statewide Action Plan to develop a comprehensive, community-based system of care that encompasses physical, psychological, educational, vocational, and social aspects of TBI services. This Action